To:

Gill, Ayesha

Subject:

Immunization Registry and HIPAA

The question has been asked as to whether disclosures of protected health information by Medi-Cal managed care plans to the Statewide Immunization Information System (SIIS) violate provisions of the Health Insurance Portability and Accountability Act (HIPAA).

After reviewing the HIPAA Privacy Rule and Health and Safety Code section 120440, the SIIS statute, and consulting with house counsel for the Medi-Cal program, I have concluded that such disclosures do not violate the HIPAA Privacy Rule.

Under 45 CFR section 164.512, a health plan may disclose protected health information without an individual's authorization for public health activities and purposes to a public health authority authorized by law to collect such information for the purpose of preventing or controlling disease and the conduct of public health surveillance, public health investigations, and public health interventions. This permission to report is very broad and includes for the purposes of controlling disease (such as by immunizations) and the conduct of public health interventions (such as by tracking the immunization status of children.) HIPAA says nothing about whom the public health authority may redisclose to. In fact, the SIIS is itself not covered by HIPAA and may redisclose to anyone to whom disclosure is permitted by the statute.

The Medi-Cal program has concluded that the SIIS performs extremely important functions which serve to improve coordination of care, improve quality of care for enrolled beneficiaries, and ensure adequate delivery of the Medi-Cal immunization benefit. The SIIS also performs key functions which serve to increase the likelihood that enrollees will receive scheduled immunizations, including provider and patient reminders. The SIIS also allows plans to track immunization status of enrollees, including receipt of immunizations when individuals have either not been Medi-Cal beneficiaries or enrolled in a different plan. In the absence of the SIIS, enrollees are more likely to receive duplicative/unnecessary immunizations, at State expense.

Therefore, disclosures to the SIIS by Medi-Cal managed care plans are directly connected with the operation of the Medi-Cal program and are permitted by HIPAA as permissive disclosures for public health prevention and intervention purposes. Medi-Cal managed care plans are not prohibited by law from making such disclosures.

Roberta M. Ward, Senior Counsel California Department of Health Services (DHS) DHS Privacy Officer

To:

Smith, Jeanette (DHS-OLS)

Cc:

Nolan, Sheila; Otto, Mark; Ferber, Harold

Subject:

RE: Immunization Registry

The actual language of 45 CFR section 164.512 states: A covered entity (read health plan or provider) may disclose protected health information without the authorization of the individual for public health activities and purposes to (i) a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease including, but not limited to the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions." This permission to report is very broad and includes for the purposes of controlling disease (such as by immunizations) and the conduct of public health interventions (such as by tracking the immunization status of children). HIPAA says nothing about whom the public health authority may redisclose to. In fact, the Immunization Registry is itself not covered by HIPAA and may redisclose to anyone to whom disclosure is permitted by the statute. The statute at Health and Safety Code section 120440 is quite specific in allowing health care providers and plans, unless the parent or guardian refuses to permit record sharing, to disclose certain data elements to the Immunization Registry, which may redisclose all but one data element (address and telephone number) to other providers taking care of the patient and to schools, child care facilities and family child care homes to which the child is admitted, and WIC service providers providing services to the person, as well as health care plans arranging for immunization services, and county welfare departments assessing immunization histories.

So, it is my opinion that HIPAA does not forbid this sharing of immunization information with the Registry by health plans. According to Frank Debernardi and Linda Rudolph, the sharing by Medi-Cal managed care plans is connected to the operation of Medi-Cal. So there would appear to be no Medi-Cal prohibition. However, the statute does not require the health plans to share information. And HIPAA just permits public health disclosures. This particular disclosure is **not required by law**, so no plan can be forced to report.

If the redisclosure provision of the law is problematic, then plans may decide whether to participate and whether to restrict redisclosures.

-----Original Message-----

From:

Smith, Jeanette (DHS-OLS)

Sent:

Tuesday, March 18, 2003 4:25 PM

To:

Ward, Roberta (DHS-OLS)

Subject:

RE: Immunization Registry

On HIPAA: it seems to be the opinion of Dawn Goodman, Privacy & Security Officer for San Joaquin Public Health Services, that re-disclosure of member protected health information to non-providers (from the immunization registry) removes this register from the category of "public health surveillance to prevent or control disease per 45 CFR sec. 164.512(b)(1)(i). Thus sharing with the immunization registry would not be permitted either under HIPAA or MediCal.

Dr. Dales is concerned that there is a meeting next week with the various local health systems, including San Joaquin public Health Services, and that this issue needs to be resolved before such a meeting, so that other counties don't buy in on this interpretation.

Dr. Dales is ready to postpone the meeting if that is necessary. If I don't hear from you before our telephone tomorrow afternoon, I will suggest that he postpone the meeting until we have some answers (interpretations) to give him.

Please let me know what you think about Ms. Goodman's interpretation. Thanks.

----Original Message----

From: Ward, Roberta (DHS-OLS)

Sent: Tuesday, March 18, 2003 4:14 PM

To: Smith, Jeanette (DHS-OLS)

Cc: Nolan, Sheila(DHS-EX-OOLS); Otto, Mark (DHS-OLS); Ferber, Harold (DHS-OLS)

Subject: Immunization Registry

Unfortunately, the meeting was moved to Sheila's office. We talked briefly about the immunization registration issue. Sheila and Mark are looking into it further, as it involves whether this disclosure is for a purpose directly connected to the operation of the Medi-Cal program.

From:

Gill, Ayesha (DHS-DCDC)

Sent:

Tuesday, March 25, 2003 2:46

To:

Ward, Roberta (DHS-OLS)

Cc:

Fanelli, Susan (DHS-PSD)

Subject:

FW: SIIS meeting on April 8, 2003

Importance: High Hello Roberta,

I am finalizing the plans for the Statewide Immunization Information System (SIIS) meeting on April 8-9, 2003, am writing to ask if you will be able to accept our invitation to speak on April 8 at 10:00 am.

Although I originally asked you to speak on the effect of HIPAA on our regional registries, considering the question of the interpretation of Medicaid rules which has arisen, it would be very helpful if you could also inform our registry people about the state position on this. I really appreciate the time that you and other legal counsel have taken to investigate and inform us about these issues and their interpretation for the registries.

I look forward to hearing from you. I hope that you will be able to participate in our meeting and that we will have a chance to meet.

Ayesha Gill

----Original Message-----

From: Gill, Ayesha (DHS-DCDC)

Sent: Wednesday, March 12, 2003 5:24 PM

To: Ward, Roberta (DHS-OLS) **Cc:** Fanelli, Susan (DHS-PSD)

Subject: SIIS meeting on April 8, 2003

Hello Roberta,

I spoke with Susan last week about seeking a speaker on the topic of the impact of HIPAA compliance on our regional immunization registries for our next statewide meeting. Susan told me she had spoken with you and asked that I send you some additional information about our organization, the meeting itself, and the probable questions from participants. That is the purpose of this email. In addition, we received a troubling letter from one of our regional registries about a Medi-Cal Managed Care Health Plan, which was intending to participate in the registry, but has decided not to for reasons associated with Medicaid policy, not only the new HIPAA requirements. I will forward the email with the attached letter to you. I would be very grateful if you could review it and let us know if you think the Medicaid rules will be a legal barrier to health plans joining the immunization registry.

The Statewide Immunization Information System (SIIS) is an immunization registry that was authorized by legislation in 1995 (AB254). Additional legislation expanding the registry system was enacted twice since then, and the current legislation is AB1748 (2000), which amended Section 120440 of the Health and Safety Code. I'm attaching a description of the SIIS (SIIS Story) to give you an idea of what the purpose and history of the registry is.

We hold statewide meetings twice a year, to which our stakeholders are invited. Our stakeholders include public health staff from the local and state levels (who developed the registries), public and private healthcare providers of immunizations, including health plans, and other interested parties. We have been averaging about 120 participants at our meetings. I am attaching a preliminary agenda, which has the place and time of the April 8-9 meeting. The talk that we hope you will be able to give is half an hour at mid morning on Tuesday, April 8, in Oakland.

Our registry staff and participants are very concerned about the possible impact of HIPAA Privacy and Security

requirements. The purpose of the registry is to integrate the immunization history from different providers into one complete and up-to-date record for each patient. The information is shared with the providers and other users who serve the patient, but we have strict privacy and security rules for registries and their participants, The purpose of the registry is to make the records available electronically to improve the patient's care. Some of the providers, who were interested in joining the registry, are becoming concerned that they might be in danger of non-compliance, because the registry can also be accessed by schools, WIC agencies, and CalWORKS. The registry managers would like to have a definitive statement about the HIPAA compliance of the registry to share with the providers. In my conversation with Sybil O'Malley at OCR, however, she told me that HIPAA is so broad and the situations covered so varied that they would not put out such a statement for fear of it's being improperly applied. I could send you some more specific questions that have arisen, if you like.

Since you deal not only with HIPAA, but also other legislation and matters regarding privacy rules in California, you would be able to give a broader view of the privacy considerations to the participants at the SIIS meeting. I would be very pleased, if you could participate in our meeting.

I have gone on at some length, but I wanted to give you the necessary background. Please let me know if you have any questions.

Thank you.

Ayesha Gill, PhD SIIS Coordinator DHS Immunization Branch Phone: 510-540-3452

From:

Otto, Mark (DHS-OLS)

Sent:

Thursday, March 20, 2003 3:07 PM

To:

Dales, Loring (DHS-DCDC)

Cc:

Ward, Roberta (DHS-OLS); Smith, Jeanette (DHS-OLS); Kisoki, Lorna (DHS-MMCD);

Rudolph, Linda (DHS-MMCD); Gill, Ayesha (DHS-DCDC)

Subject:

RE: Immunization registry

In response to your three e-mails concerning the above-referenced issue, I have been following this string of e-mails over the last week or so, though I have very little knowledge regarding the immunization registries. With respect to uses and disclosures allowed under HIPAA, I would defer to Roberta Ward, the DHS Privacy Officer, who is very knowledgeable in that area. However, as these e-mails have discussed, such use and disclosure issues often find their way to the "purposes directly connected to the administration of the Medicaid/Medi-Cal program" standard, the stricter federal and state standard that preempts HIPAA rules and applies to Medi-Cal plans. (Please see 42 U.S.C. 1396a(a)7, 42 C.F.R. 431.300, and W & I Code Section 14100.2, the latter which applies to Medi-Cal Plans pursuant to 45 C.F. R. 164.504(e)(2)). As you can imagine, and are probably aware, determining what is directly connected to the administration of Medi-Cal is often difficult, and in this instance I was somewhat concerned when I read suggestions that disclosures to the Immunization Registries met this standard because CMS was willing to pay FFP.

Having now performed some research on this issue, I feel that Roberta Ward's reasoning and opinion in her e-mail of March 18 is well thought out and covered all of the issues and relevant statutes, including Health & Safety Code section 120440, which as Roberta pointed out, provides the controlling language regarding redisclosure since the Immunization Registry is not covered by HIPAA, nor does HIPAA discuss redisclosure by the public health authority. With respect to whether the purposes of the immunization registry disclosures are directly related to the administration of Medi-Cal, I will plagiarize from Linda Rudolph's eloquently stated e-mail dated March 11:

"The registries perform extremely important functions which serve to improve coordination of care, improve quality of care for enrolled beneficiaries, and ensure adequate delivery of the Medi-Cal immunization benefit.

The registries allow plans to track immunization status of enrollees, including receipt of immunizations that are received when individuals have either not been Medi-Cal beneficiaries or enrolled in a different plan. In the absence of the registry information, enrollees are more likely to receive duplicative/unnecessary immunizations, at State expense.

The registries also perform key functions which serve to increase the likelihood that enrollees will receive scheduled immunizations, including provider and patient reminders. Reminders have been proven to improve immunization rates. Medi-Cal Managed Care immunization rates, as measured by HEDIS, have substantial room for improvement, and we should be encouraging plans to utilize all available tools to improve. Registries are a key tool for immunization rate improvement for our plans.

The registries also permit plans to provide feedback to providers on immunization practices, another proven effective tool in improving immunization rates."

In my opinion, such disclosures define "directly connected to the purposes of the Medi-Cal program." I hope this has been of some assistance.

Mark E. Otto Staff Counsel DHS-Office of Legal Services (916) 657-0436 motto@dhs.ca.gov ----Original Message----

From: Dales, Loring (DHS-DCDC)

Sent: Thursday, March 20, 2003 1:46 PM

To: Otto, Mark (DHS-OLS)

Subject: FW: Immunization registry

Mr. Otto, here's the third and (I think) final installment of what I'm sending you.

Thanks for any consultation you can provide us on this matter.

----Original Message----

From: Horlick, Gail [mailto:gyh6@cdc.gov]

Sent: Tuesday, March 18, 2003 11:16 AM

To: 'Dales, Loring (DHS-DCDC)' Cc: Gill Ayesha (Gill, Ayesha) Subject: RE: Immunization registry

Loring,

I have not heard of this type of legal barrier being raised in other states. However, the language in the Ca Medi-Cal statute "...for purposes directly connected with the administration of the Medic-Cal program..." is language that I believe tracks the language in the federal Medicaid law, so similar language is likely to exist in other states.

I agree that the Medi-Cal law is more stringent than HIPAA. However, HIPAA does not preempt the CA public health law authorizing the registry and permitting disclosure with consent. I am fairly certain that a preemption analysis of various state and federal laws is being conducted in CA but I just can't think of who might be doing that. Is there a CA Health Care Foundation? I feel like I heard that at one of the hearings. At any rate, I will try to make some inquiries about this issue.

I don't agree with the interpretation in #2 of the email to Ayesha, that "the premise for disclosure related to HIPAA is for public health activities, in this case surveillance for the prevention and control of communicable diseases" and that the redisclosure to other agencies does not qualify as public health surveillance. And in the letter, it states that "redisclosure to those agencies does not appear it will achieve the purpose of preventing or controlling disease'.

HIPAA (164.512(b) (i) permits disclosure to an authorized public health agency "...for the purpose of preventing or controlling disease.....and the conduct of public health surveillance, public health investigations, and public health interventions..." I interpret disclosure to a registry as a means of preventing or controlling disease, and I have also heard the interpretation that it is an intervention. At any rate, I disagree that the disclosure to other agencies is for administrative purposes. While the other agencies may not administer treatment directly, a school or day care center that uses the information to refer for immunizations, or will not admit a child who has not been properly immunized, is in my view, preventing or controlling disease.

Before I forget, I have been meaning to send you this site for a summary of CA privacy laws: http://www.healthprivacy.org/usr_doc/CA2002.pdf

Loring, I'm sorry I can't offer more right now as this is the first I have heard of this. Please keep me posted.

Gail

Gail Horlick, MSW, JD Public Health Analyst Immunization Registry Support Branch CDC National Immunization Program

404-639-8345

fax: 404-639-8171

----Original Message----

From: Dales, Loring (DHS-DCDC) [mailto:LDales@dhs.ca.gov]

Sent: Monday, March 17, 2003 2:34 PM

To: Debernardi, Frank (DHS); Goldwater, Jason; Horlick, Gail, JD

Cc: Gill, Ayesha (DHS-DCDC)

Subject: FW: Immunization registry

Importance: High

We have been forwarded the communication (the attachment) from a Medi-Cal (California's Medicaid program)-contracting Managed Health Care plan stating that, per a California Medi-Cal statute (Welfare and Institutions Code Section 14100.2), they are prohibited from sharing any information on theirn identified Medi-Cal beneficiary clients with immunization registries in our state.

It is not clear to me whether this California statute also may prohibit non-public health care providers (e.g., private physicians and health care facilities contracting directly or indirectly with Medi-Cal to care for beneficiaries) from this activity.

I abstract here what seems to be the key language from the state statute cited in the attached letter - Welfare and Institutions Code Section 14100.2:

- "(a) All types of information ... concerning a person, made or kept by any pubic officer or agency in connection with the administration of any provision of this chapter ... shall be confidential, and shall not be open to examination other than for purposes directly connected with the administration of the Medi-Cal program...
- (b) Except as provided in this section and to the extent permitted by federal law or regulation all information about ... recipients ... to be safeguarded includes, but is not limited to, names and addresses, medical services provided ... and medical data ...
- (c) Purposes directly connected with the administration of the Medi-Cal program ... encompass those administrative activities in which the State Department of Health Services and its agents are required to engage to insure effective program operations. These activities include, but are not limited to ... providing services for recipients ..."

Frank, are you familiar with this statute and its possible applicability as indicated in the attached letter from a Medi-Cal Managed Care-contracting health plan.

Jason, Gail: Are you aware of other states where a similar state Medicaid program statute exists and has been raised as a legal barrier prohibiting at least public providers of health care services to Medicaid beneficiaries from sharing patient/client information with immunization registries?

Thanks very much for any information/perspective you can provide here. We have a meeting with Medi-Cal Managed Care plans scheduled for ten days from now - March 27 - to discuss their participation in California's immunization registry system. We are not sure we should go ahead with this meeting until the above-described issue is resolved.

----Original Message---From: Gill, Ayesha (DHS-DCDC)

Sent: Tuesday, March 11, 2003 12:10 PM

To: Dales, Loring (DHS-DCDC); Backer, Howard (DHS-DCDC)

Subject: FW: Immunization registry

Importance: High

----Original Message----

From: Colleen Tracy [PHS] [mailto:ctracy@sjcphs.com]

Sent: Friday, March 07, 2003 4:58 PM

To: AGill1@dhs.ca.gov

Subject: FW: Immunization registry

Importance: High

Dr. Gill,

I had your address incorrect - resending message. Colleen Tracy

----Original Message----From: Colleen Tracy [PHS]

Sent: Friday, March 07, 2003 4:51 PM

To: 'AGill@1dhs.ca.gov'

Cc: Ginger Wick [PHS]; William Mitchell [PHS]

Subject: FW: Immunization registry

Importance: High

Dr. Gill,

The Department has received the attached letter from the HIPAA Privacy and Security Officer for the Health Plan of San Joaquin, the County-operated Medi-Cal managed care plan. We are all startled by the content - she reports that

1) the health plan is legally unable to share client-identifiable data for Medi-Cal members with the immunization registry based on provisions of the Welfare and Institutions Code and federal Social Security Act; this is "reinforced" by a verbal opinion given by Roberta Ward, DHS Privacy Officer on February 19, 2003. The basic reasoning appears to be that the provisions of the Medi-Cal Program on sharing data are more stringent than HIPAA and therefore prevail.

2) the health plan may not share protected health information on Healthy Families members, despite the specific provisions of the California Health & Safety Code permitting data sharing by health plans with immunization registries, because the premise for disclosure related to HIPAA is for public health activities, in this case surveillance for the prevention and control of communicable diseases and they have determined that the redisclosure of member information through the registry to other agencies such as schools, WIC and welfare departments does not qualify as public health disease surveillance.

She goes on to request we remove any member records from the registry.

We waited until we received the formal correspondence (today) to notify you. We had not put member records into the registry but had data on CDs. We were continuing to work with them on assuring the mechanism for giving parents/guardians the required notice/disclosure of record sharing was in place and that the plan did not send us records for which a refusal to share was received by the plan.

Dawn and I work together generally as we both oversee HIPAA implementation for our departments. She and I had talked a few times during the past 2 months about the impact of HIPAA on immunization registries. I had recently sent her the Health & Safety code statute as well as information from CDC etc. Based on our conversations, the health plan was concerned at the number of non-health care provider agencies that could access the registry. I had also been concerned when I first got to San Joaquin about what agencies were able to actually create and modify immunization records, as the initial premises for data sharing were based on health care providers sharing information for treatment (determining histories from the registry and updating the record) and the responsibility of local health officers to prevent and control communicable diseases. The original statute has been considerably expanded to permit access by other agencies for non-treatment,

administrative use purposes. However, I thought Dawn and I were working toward the health plan possibly including some language in their Privacy Notice that sharing information with the local registry was a routine disclosure, in addition to the notice/disclosure required by the Health & Safety Code.

I know this information will be important to the State as well as our regional project. We have destroyed the CDs with their data, based on their request. I am available at (209)468-3410 to discuss this further. The health plan knows that I intend to share the communications with you.

Happy Friday afternoon...

> Colleen,

----Original Message---From: Dawn Goodman [HPSJ]
Sent: Wednesday, March 05, 2003 5:49 PM
To: Colleen Tracy [PHS]
Subject: Immunization registry

> Thought I would give you some advance notice of our bad news. HPSJ will
> not be able to disclose member data to PHS for the registry. I officially
> put our position in writing (see attached - hard copy is in the mail). I
> only recently found out that the Department of Health Services strictly
> forbids such disclosures for our Medi-Cal population and, with regard to
> Healthy Families, I just could not get comfortable with the redisclosure
> to schools, WIC, etc. Anyway, I put all the legal citations in the letter
> so your team will understand exactly the basis for our decision. I can
> tell you that our systems were already built, the opt-out form had been
> mailed, and everyone here was ready to go. Those activities pertaining to
> provider and member communications we are certainly expecting to continue
> to support.
>
> Please call if you wish to discuss,
> Dawn
> <<Immunization registry.doc>>

March 5, 2003

Ms. Colleen Tracy Deputy Director San Joaquin Public Health Services P O Box 2009 STOCKTON CA 95201

RE: Immunization Registry

Dear Colleen:

In light of the soon to be enforced HIPAA Privacy Rule, I was asked to examine the feasibility of the Health Plan of San Joaquin's participation in the County immunization registry as it pertains to our Medi-Cal and Healthy Families membership. In addition to the Privacy Rule, I also considered the Welfare and Institutions Code 14100.2 and Title XIX of Social Security Act as they affect the Medi-Cal Program; and the Health and Safety Code §120440 and Appendix E, Immunization Services dated August 20, 2002, of the Memorandum of Understanding between HPSJ and PHS currently pending approval from the Department of Health Services.

Looking first at our Medi-Cal membership, we find that HPSJ is prohibited from sharing any member data that includes name, address and medical services provided "other than for purposes directly connected with the administration of the Medi-Cal program (Welfare and Institutions Code). This is reinforced in Section 1902(a)(7) of the Social Security Act that requires that "a State plan for medical assistance must provide safeguards which restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan". Providing further clarification was the Privacy Officer of the state Department of Health Services, Roberta Ward, during a teleconference with health plans on February 19, 2003. During the call, whose purpose was to discuss the HIPAA Notice of Privacy Practices that DHS and Medi-Cal plans must issue to members, Ms. Ward pointed out that many disclosures allowed under HIPAA are prohibited under Medi-Cal and because Medi-Cal is more stringent those provisions supercede HIPAA. One health plan specifically asked if this applied to immunization registries. Ms. Ward confirmed that disclosing member data to an immunization registry is not permitted under the Medi-Cal program.

Page 2 Immunization registry March 5, 2003

Since Healthy Families is not affected by either W&I Code or the Social Security Act, I next reviewed HIPAA permitted disclosures for public health activities against the Health and Safety Code and Appendix E of the MOU. As you are aware, the H&S Code permits HPSJ to disclose member data to PHS. Further, HPSJ understands that public health staff operating the immunization registry considers this "public health surveillance" as described and allowed under HIPAA. HPSJ would agree if our disclosure of member data were exclusively held by PHS. Instead, H&S Code permits redisclosure by PHS to agencies, not limited to, schools, child care facilities, service providers for WIC and the county welfare department. Specifically, protected health information eligible for redisclosure includes name of child and parents, child's date of birth and other nonmedical information necessary to establish the child's unique identity. HPSJ feels that redisclosure of member protected health information to non-providers such as the agencies listed above does not qualify as public health surveillance as described under HIPAA. Redisclosure to those agencies does not appear it will achieve the purpose of preventing or controlling disease (45CFR§164.512(b)(1)(i).

As you might conclude, HPSJ regretfully cannot provide member information for the immunization registry. With regard to the member data that HPSJ has already disclosed to PHS, we feel obligated to request that those records be removed from the immunization registry as long they remain accessible by the agencies referenced earlier.

It should be noted that the surveillance responsibilities of HPSJ under Appendix E of the MOU does not include our disclosure of member immunization records. HPSJ is able to perform our surveillance responsibilities as presently reflected in Appendix E through provider education classes and fax alerts. As well, HPSJ is still committed to assisting with provider education and issuing reminders to members to seek immunizations.

If I may provide clarification, or you wish to discuss further, please feel free to contact me.

Sincerely,

Dawn Goodman
Privacy and Security Officer

cc: Robin Morrow, Health Educator, HPSJ
Jerry Sonderman, Data and Security Manager, HPSJ